

REMARKS

After amendment, claims 1-3, 6-7 and 89-93 are pending in the present application. Claims 4-5 and 8-22 are cancelled without prejudice pursuant to the Examiner's restriction requirement. Claims 23-88 were previously cancelled without prejudice. The amendment has been made to the original claims to reflect the elected invention. No amendment was made to distinguish over the art of record. It is respectfully submitted that the amended claims now meet the requirements of 35 U.S.C. and are clearly patentable over the art of record. A review of the present claims in comparison to the disclosures cited against the instant application evidences that the presently claimed compositions are clearly patentable over the disclosures of Cohn, US patent no. 4, 826,945 ("Cohn"), in view of Newkirk, US patent no. 4,094,797 ("Newkirk").

The Examiner has rejected original claims 1-3, 6 and 7 under 35 U.S.C. §103 as being invalid over Cohn, in view of Newkirk for the reasons which have been stated in the office action. Essentially, it is the Examiner's view that Cohn teach multi-block polymers comprising diblocks of poly(hydroxycarboxylic acid) and poly(oxyalkylene) ethers, but not endcaps on such polymers. The Examiner cites Newkirk for teaching the endcapping of polyoxyalkylene compounds with an aliphatic monocarboxylic acid. Improved resistance to oxidation is disclosed. From these combined disclosures the Examiner considers that it would have been obvious or one of ordinary skill in the art to endcap the terminal polyoxyalkylene block of the polymers of Cohn as taught by Newkirk to achieve the beneficial effect of improved resistance to oxidation of Newkirk. Applicants respectfully traverse the Examiner's rejection.

The present invention is directed to novel crosslinked diblock polymers comprising AB diblocks which are crosslinked, where A is a polyester block and B is a polyether (poly)oxyalkylene block which is end-capped with a non-reactive group. Polymeric compositions according to the present invention exhibit unexpected activity as storage stable compositions of definitive structure, the size or molecular weight of which can be fairly easily controlled and modified. Compositions

may vary greatly in viscosity and in form with contemplated compositions being used primarily as viscous solutions and gels, although numerous other forms are clearly contemplated by the present invention. The compositions, because they are based upon diblocks which are end-capped, generally have molecular weights which are significantly reduced in comparison to triblock/multiblocks, for example, those which are disclosed in Cohn. The advantage of the present polymers is that they can be used to produce biodegradable or bioerodible viscous formulations which exhibit varying viscosities for purposes of providing unique polymers, in particular, post-surgical polymers which can be delivered to a site within a patient's body to prevent adhesion formation. This can be done despite the crosslinked structure of exemplary polymers of the present invention. It is the combination of stability as well as the ability to readily control viscosity of the polymeric materials (at low or high viscosities, as defined by the length of the A or B block and the amount of crosslinking which occurs) which makes these polymers patentably distinguishable over the polymers disclosed by Cohn, in view of Newkirk. Compositions according to the present invention are particularly attractive for use in medical applications, and in particular, as barriers for preventing or reducing adhesion and in delivering drugs and other bioactives to patients. The relatively low viscosity in certain applications, gives advantageous structural features which enable polymers according to the present invention to be delivered in applications where films are contraindicated. Numerous other uses for the present compositions are also contemplated by the invention.

The Examiner has rejected original claims 1-3 and 6-7 as being invalid under 35 U.S.C. §103 as being unpatentable over Cohn, in view of Newkirk. Applicants respectfully disagree.

Cohn, contrary to the Examiner's reading, does not disclose or suggest polymers which render the present invention unpatentable. In particular, Cohn is directed to certain chain-extended ABA triblock polymers which are unrelated to the present invention. As indicated, the present invention is directed to diblock polymers, not triblock polymers. In Cohn, ABA triblock polymers are produced wherein the two A blocks are made by building polymeric chains off of a central B block comprised of polyethylene oxide or another polyoxyalkylene block. The A blocks are then

chain-extended to produce the Cohn disclosed compositions. There is no disclosure or hint that diblocks according to the present invention are desirable or even should be made or that end-capping is desirable. Indeed, Cohn is silent on the desirability of the use of diblocks.

The Examiner has read Cohn as teaching certain diblock/multiblock polymers. It is respectfully submitted that the Examiner has actually misread Cohn as disclosing or teaching diblock polymers. It is respectfully submitted that Cohn does not teach crosslinked diblock polymers, but rather teaches chain triblock ABA-type polymers or multi-block AA'B-type multiblock polymers, which are produced by transesterifying the original ABA triblock polymers. It is noted that in each instance where Cohn discloses a polymer, that polymer is based upon a triblock polymer (where a or b is 0), generally a chain-extended triblock polymer. There is simply no place in the specification of Cohn the Examiner can point to as disclosing a diblock polymer, similar to that used in the present invention. There is clearly no teaching in the specification of Cohn which teaches crosslinked diblock polymers according to the present invention. Note that where a and b are greater than 0, the resulting polymer is an AA'BAA'-type multiblock polymer which is produced by transesterification of the basic ABA triblock polymer disclosed therein. Those composition are clearly not the present invention.

The specification of Cohn (at column 9, line 35) speaks to the use of the chain-extended triblock polymers disclosed therein for use in fabrics, wherein more than one type of polymeric filament may be used. All of the examples of Cohn refer to the preparation of triblock polymers. In sum, contrary to the Examiner's contention, there is simply nothing in Cohn which suggests that diblock polymers may be made or advantageously used as in the present invention. Consequently, it is respectfully submitted that there is absolutely no disclosure or suggestion which can be gleaned from Cohn which either discloses diblock polymers or would motivate one of ordinary skill to produce the diblock polymeric compositions according to the present invention.

Note that Cohn discloses a number of uses of the polymers disclosed therein at column 3, lines 64-68 and column 4, lines 12, which suggest that the polymers will have high molecular weight and a structural integrity reflective of the use of such polymers in surgical devices such as sutures, ligatures, needles, surgical clips, staples, wound coverings (films), screws, etc. which clearly emphasize and teach one of ordinary skill the importance of high molecular weight polymers. As has been indicated, one of the advantages of the compositions of the present invention is that because of the diblock configuration (in contrast to the triblock configuration of Cohn) the molecular weight of the polymers may be more readily controlled to a lower molecular weight with structural integrity and reduced viscosity because the present compositions avoid the use of an additional polymeric A block within the structure of the polymer. The diblock polymers according to the present invention may be used to advantageously produce materials which have relatively low viscosities which find use in applications such as in post-surgical applications after minimally invasive surgical methods (e.g., laparoscopy). There is simply nothing in Cohn which discloses or suggests the advantages or the desirability of the present compositions. If anything, Cohn emphasizes the need for the structural integrity of polymers and a high molecular weight triblock (relative to the diblocks of the present invention) polymeric structure. In such respects, Cohn actually *teaches away* from the present invention.

The Examiner further cites Newkirk against the present invention. Nothing in Newkirk can be used to embellish the disclosure of Cohn to render the present invention obvious. Newkirk discloses oxidation stable fiber lubricants which are based on the polymeric structure set forth in columns 3 and 4 of Newkirk. These are endcapped polyoxyalkylene polymers. While Newkirk may disclose the advantageousness of end-capping certain multiblock polyoxyalkylene polymers which are unrelated to those of in the instant invention, certainly Newkirk in no way motivates the basic polymeric structure of the present invention, the disclosure or suggestion of which is absent in Cohn. In combining Cohn and Newkirk, one is still left with a basic polymeric structure which is not a polymer based upon AB blocks according to the present invention. Even assuming *arguendo*, that Newkirk does motivate the end-capping of the

polymers of Cohn¹, the resulting compositions would not bring to mind the present polymeric compositions because of the clear distinction between the polymeric compositions of the present inventions and the polymers which are disclosed in Cohn. By combining Cohn and Newkirk, assuming that it was even reasonable to do so, would result in *at best* an end-capped triblock polymeric composition or an end-capped AA'BAA'-type polymeric composition², neither of which would relate to the present invention or render the present invention unpatentable.

Consequently, for the reasons which are presented hereinabove, it is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

¹ Applicants concede this point only for the sake of argument-it is clear that Newkirk does not motivate end-capping where oxidation is not a critical concern and its protection not a critical requirement-because this is not taught in Cohn. Also, end-capping would result in limiting the molecular weight of the Cohn polymers- something which is undesirable based upon the uses disclosed for the Cohn polymers.

² Following Cohn in transesterifying the ABA triblock polymers, one would more likely be left with a polymer which could not be easily characterized- even if it were end-capped.

Applicant has cancelled 17 claims (two independent) and added 5 dependent claims. No fee is believed to be due for the presentation of this amendment. Small entity status pertains to this application. The Commissioner is authorized to charge any deficiency in fee or to credit any overpayment to deposit account 04-0838.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C., 20231, on January 24, 2006.


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